



U.S. Department of Justice

United States Attorney  
Southern District of New York

86 Chambers Street, 3rd Floor  
New York, New York 10007

MEMO ENDORSED

June 10, 2019 The parties are directed to  
submit status updates at three-week  
intervals, beginning today.

SO ORDERED:

*Paul G. Gardephe*  
Paul G. Gardephe, U.S.D.J.

Re: *United States v. Novartis*, No. 11 Civ. 0071 (PGG) Dated: *June 11, 2019*

Dear Judge Gardephe:

At Your Honor's request, we write respectfully on behalf of the parties to update the Court on the parties' progress toward reaching a final settlement of this matter.

Novartis and the United States have made significant progress on finalizing the proposed settlement, and anticipate that it will be substantially complete by June 18. In particular, the monetary aspects of the settlement have been submitted for expedited approval by the Commercial Litigation Branch of the Department of Justice, and we are informed that this process should be completed by June 18. Moreover, in the past weeks, Novartis and the United States have exchanged a number of drafts of the proposed settlement agreement, and have had several calls to discuss outstanding issues.

Despite this progress, the parties likely will not be in a position to execute the federal settlement agreement on June 18. As we previously reported to the Court in our letter of May 19, as part of the settlement process, Novartis is negotiating the terms of a new Corporate Integrity Agreement ("CIA") with the Office of Inspector General of the U.S. Department of Health and Human Services ("OIG-HHS"). This is because the conduct that allegedly creates liability under the False Claims Act also implicates OIG-HHS's permissive exclusion authority under 42 U.S.C. § 1320a-7(b)(7). Exclusion is a purely administrative remedy for which OIG-HHS has exclusive jurisdiction.

Where appropriate, OIG-HHS may agree to waive permissive exclusion of a defendant settling a FCA matter, provided that the defendant is willing to enter a CIA with OIG-HHS. CIAs require defendants to implement a specified set of compliance obligations including the establishment of a compliance officer and compliance infrastructure, training, a risk assessment program, and outside monitoring by an independent review organization. The CIA also imposes interim and annual reporting obligations on the defendant. OIG-HHS drafts and negotiates the CIA with the defendant. A CIA can be a lengthy document (with several appendices) if the

defendant is a large, complex organization. Moreover, to increase their effectiveness, CIAs are tailored to the specific structure, functions, and operations of the defendants. Given their complexity, the drafting and negotiation of a CIA for a large organization typically requires a few months. To provide context, the 2010 CIA entered into between Novartis and OIG was 80 pages in length, and contained detailed provisions that were specific to Novartis's business model.

In light of Your Honor's direction that the settlement be finalized as quickly as possible, OIG-HHS and Novartis are working diligently to reach agreement on the terms of a CIA. Due to the complexity and importance of this process, however, OIG-HHS requires additional time and estimates that this process will take another 60 days to complete.

The draft federal settlement agreement expressly contemplates that OIG-HHS, which will be a signatory to the agreement, will waive permissive exclusion in exchange for the CIA. Accordingly, the agreement cannot be executed until the CIA has been finalized. Novartis and the United States therefore respectfully request that the parties be granted until August 13 to attempt to finalize and execute the settlement papers. The parties can provide the Court with periodic status updates on the progress of the settlement on any schedule the Court would prefer.

For purposes of preserving confidentiality, the parties request that this letter not be publicly docketed until the parties have reached a final settlement.

We thank you for your consideration of these requests.

Respectfully,

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